UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation

No. MD-15-02641-PHX-DGC

EXHIBIT INDEX

PLAINTIFFS' RESPONSE TO DEFENDANTS C. R. BARD, INC.'S AND BARD PERIPHERAL VASCULAR, INC.'S MOTION TO EXCLUDE THE OPINIONS OF THOMAS KINNEY, M.D., ANNE CHRISTINE ROBERTS, M.D., AND SANJEEVA KALVA, M.D.

Exhibit 1	Kinney Deposition Excerpts 6-17-17
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EXHIBIT 01

EXCERPTS FROM DEPOSITION TRANSCRIPT OF THOMAS KINNEY, M.D.

June 17, 2017

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS
PRODUCTS LIABILITY MD-15-02641-PHX-DGC
LITIGATION

VIDEOTAPED DEPOSITION OF THOMAS KINNEY, M.D.

La Jolla, California

Saturday, June 17, 2017

Volume I

Reported by:
Gail E. Kennamer, CSR 4583, CCRR

engineering and 1983 when you started medical school?

A. Yes, I did. I worked for NASA for a year and a half doing aeronautical design and wind tunnel.

And then I worked for Thomas Fogarty as a bioengineer designing medical devices, prototyping medical devices, and doing FDA submissions for four years.

Q. Why don't we start with the job you took immediately after receiving your master's degree in mechanical engineering. Was that the job with NASA?

A. That was the job with Thomas Fogarty.

Q. Okay. And what specifically did you do for Dr. Fogarty?

A. We were designing angioplasty balloons. We did pathophysiology experiments with mechanism of angioplasty.

We designed vascular clamps.

He was a referral person for many other physicians that were interested in innovation and design, so we did some ureteral dilators for one of his urology colleagues.

I designed a vascular clamp for one of Dr. Fogarty's former partners, Dr. Pat Daily, who was here at San Diego.

We also got involved in designing a cardioplegia jacket to do cardiac bypass. And that was a project I continued when I went to medical here, and that project we actually did a 510(k) submission for FDA as well.

Q. You mentioned a number of medical devices that

you worked on during your time with Thomas Fogarty.

How many of those medical devices involved a 510(k) application?

A. As I recall, there were two. At least two that we did.

Q. That was the cardioplegia jacket?

A. Yeah.

And I'm pretty sure we did a vascular clamp as well.

Q. You did.

So to the best of your recollection, the vascular clamp and the cardioplegia jacket both involved eventual 510(k) submissions?

A. Correct.

Q. Did you work on the content of those 510(k) submissions?

A. I did. I did.

Q. What do you recall doing with regard to the 510(k) submissions for those two products?

A. We -- We did in vitro and ex vivo studies to confirm the performance characteristics of those devices and provided data.

And then we submitted those as -- as applications. And as I recall, the FDA had specific things that we had to fill out for that. We had the right instructions for use in there as well for the labeling. I kind of recall

doing that.

And we submitted it and waited to see what their responses were, and then there were questions, as I recall, and we -- we addressed those.

Q. Have you done any work with 510(k) applications in the last 30 years?

A. No, I have not.

Q. So would it be fair to say that you're not familiar with the current regulations regarding 510(k) applications?

MR. JOHNSON: Form.

BY MR. BROWN:

Q. You can answer.

A. I would say -- Yeah, I imagine there has been changes. I have not looked at those. Those were not pleasant sites to look at. I mean, if you are challenged for sleep perhaps. But no, I have not looked at those.

MR. LOPEZ: He's not being offered as a 510(k) expert either, so...

MR. BROWN: Okay.

Q. And I assume that the same is true for the 510(k) regulations as they existed in the early 2000s, you don't have any knowledge about what those related to?

A. I wouldn't have any real knowledge of those other than what I kind of read from what Kessler wrote in

on my experience and knowledge of engineering.

So for me, it's how do you separate that from not being a designer versus being a designer? To me those -- those intersect. They are not mutually exclusive.

Q. When you are talking about evaluating the features of an IVC filter, are you talking about how those features relate clinically or some type of mechanical analysis or engineering analysis of those features?

MR. JOHNSON: Or both.

BY MR. BROWN:

Q. Or maybe both.

A. I -- I couldn't have said it better. I would say they are both related, in my mind. Again, there's mechanical aspects. It's a mechanical device. It's a mechanical interruption is what it was labeled as at one point. And so basically, if you are doing that, you are thinking about the clinical aspects of how well does it function collecting clots and staying where you put it, and the long-term performance characteristics. Those sort of issues.

Q. Have you done any type of publishing related to IVC filters with regard to analysis of the actual design specifications?

A. I don't recall. I mean, I did a big review article in 2003 that was the most downloaded paper from

the JVIR website for two years in a row, and we did -- we did talk about dimensional aspects, the size of the filters and the lengths of the filters. We might even have talked about the diameters of some of the wires. And to me, those are mechanical aspects. We didn't do -- specifically address analysis on those. It was a review article, and so it focused on all the commercially available filters that were available at the time, and I think there was also some comments about upcoming filters that were -- included the Bard filter, Recovery Nitinol filter.

Q. You touched on there a little bit about what I was trying to get at which is: Did you have any type of involvement in bench testing of IVC filters?

A. I have to say, so I have done a lot of filter workshops over the years for our Society of Interventional Radiology. So we would bring all the filters we had, and they would be on a bench top that we show physicians, and you'd squeeze them and say this is how strong this one is. And so is that bench top? In a sense, it is to me. I suppose we didn't have mechanical transducers or anything like that, so it's not high-level bench top work, but it was bench top evaluations involved.

Q. Would you describe that as more demonstrative-type bench top work?

want to clarify that.

BY MR. BROWN:

Q. All right. Do you have any education, training, or experience with regard to the contents of what should be included in IVC filter instructions for use?

A. Being an expert in IVC filters and having a 30-year experience placing filters, and considered -- I have been invited to give lectures on filters, so I -- I know a lot of about filters.

And also having written formal instruction for use for at least two other different devices, and also actually looking at multiple instruction for uses for all the other devices that I use on my daily work, while I may not be labeled as an expert in IFU, I think I can look at an IFU and understand what it's telling me or hoping to tell -- what's -- what it's trying to convey to me.

Q. Do you have any training, education, or experience concerning what an IVC filter's IFU should be required to include?

A. I don't have specific training. But again, I have written articles about things that go into IFUs. So those are the things that include indications, contraindications, the specific risks that are involved with filters. So while I'm not a -- I haven't been trained in that. I kind of -- I think I know what should

Q. In the same vein, do you practice evidence-based medicine?

A. Yes. When possible, there is -- we don't always have evidence, and so, then, we're kind of left to clinical experience. We're left to opinions.

What's really unique, I think, in the environment I work in is I work with seven or eight other interventionalists, and you can elicit comments from, I don't know, suggestions from them, so that's our approach to cases.

Q. When you are making the treatment decisions for your patients, am I correct that you are trying to base that decision on the most reliable information that you have?

A. Yes.

Q. As part of your methodology in this case, did you cherrypick data that helped advance your opinion that Bard's filters are defective?

MR. JOHNSON: Form.

THE WITNESS: I don't think so.

BY MR. BROWN:

Q. As part of your methodology in this case, did you ignore data that weighed against your opinions that Bard's filters are defective?

A. I don't think so.

Q. Would you agree that if you did ignore data that weighs against the opinion that Bard's filters are defective, that you would be applying the same level of intellectual rigor in this case as you apply in your private practice as a researcher and clinician?

MR. JOHNSON: Form.

THE WITNESS: I would say that I'm always willing to look at data. If you have some data to show me, I'd be happy to look at it and opine about it.

BY MR. BROWN:

Q. In drafting this report, did you take data and information out of context?

A. I don't think so.

Q. If you did take data and information out of context, would you agree that you wouldn't be applying the same level of intellectual rigor to your work in this case as you apply in your work as a clinician?

MR. JOHNSON: Form.

THE WITNESS: Again, I would say show me what you don't agree with, and we'll look at it and make an intelligent decision.

BY MR. BROWN:

Q. Okay. How was the report, which we marked as Exhibit 4, prepared?

A. We basically used the document by Dr. Kessler is

what we did, and we were -- we were asked -- we were tasked, actually, as interventional radiologists who were academicians and involved with some of the writing standards about IVC filters, and we were tasked to assess the information that was provided by Bard about their filters, and whether we thought that there was transparency in that in our approach to, say, getting consent for patients.

We were -- I lost my train of thought. Sorry.

MR. LOPEZ: If you need to refer to your report, you can, by the way.

THE WITNESS: Yeah.

You know, as clinicians that have multiple years of experience on IVC filters, we were, you know, able to make opinions about, you know, what we thought was done. We were able to assess the data that he presented, some of the experimental data, that included lab experiments and animal experiments.

Basically, it was listed as a permanent filter that had -- that was supposed to act like permanent filters that we had before.

My career and Anne Roberts' career spans the transition in filters from permanent devices to retrieval filters. And we were promised that the retrieval filters would have the same sort of performance characteristics

that our permanent devices had. And unfortunately, as the experience -- as the clinical experience accrued with the retrieval filters, we were finding that that assumption was not true, and there was -- it turned out, you know, I had done a plenary session right before Bard did your major marketing release of the Recovery Nitinol filter. The -- The SIR meeting in 2004 was in Phoenix, and we were -- my plenary session was on venous thromboembolism. And we were all excited about having the use of retrieval filters. Because we all remembered that ten-year-old kid that had a trauma that we put a filter in, and he had that filter for multiple decades, and we never felt real comfortable talking to that patient or his mother or father about what was going to happen with this multiple decades. Really, you kind of say, "We don't really know," and that's an answer that families like to hear because they -- they assume you are the doctor, you know everything and, you know, you should know these things.

So again, I lost my train of thought. Sorry.

BY MR. BROWN:

Q. All right. Well, I'm interested right now in how the report actually was physically prepared. Because we have three authors and several hundred pages of material here, and I want to get a sense as to how putting pen to paper or fingers to the typewriter this was

actually done.

A. Okay.

Q. So can you elaborate on how Exhibit 4 was prepared?

A. I -- My section, I wrote looking at the Kessler report, and I did a literature search on -- on the -- on the retrieval -- all the Bard filters, basically, from the initial animal studies. I even looked back at the Simon Nitinol data. I had experience putting in Simon Nitinol filters myself.

And so we looked at the preliminary data before some of the animal -- I looked at some animal abstracts that Dr. Kaufman wrote back when he was still at Boston, and even before that, it was approved as a device for humans.

Then I looked at Dr. Asch's studies. And that study was clearly done as a -- as just a retrievable study, and it was a short-term study, but there were -- again, you know, we talked about signals before. There were things in that study that we were concerned about in terms of there were some fractures, and there was a surprise migration of a filter that they fortunately caught because they had scheduled to retrieve it at that time.

And then there was a subsequent report that demonstrated yet another issue with a filter that came out a few years later.

Then I looked at the 510(k), and I looked at the studies that were involved in the 510(k).

What else did I look at? Then I looked at all the documents that were listed by Dr. Kessler in terms of when they did the market release which was, I recall, was in January of 2004. And then the rapidity with what sort of issues came up.

And the thing that surprised all of us that had experience with the permanent filters was we were seeing complications that we had never seen before. I do remember my point about the plenary session. What I said in that plenary session was that there were design changes made in the retrieval filter to make it retrievable; and again, we assumed that those design changes were made in a compatible fashion that the performance characteristics would be similar as a permanent filter. But I remember in that plenary session saying that it's possible that the features that make a filter retrievable may also make it migrate easily or move, and those are design tradeoffs. You know, this is the engineering aspect again, and we'll see if that's what happens or not.

And so anyway, I am getting off the track a little bit, Matthew, and I apologize. But basically, I went through the Kessler report, and went through sequentially all the different aspects of that.

Q. Is it your opinion in this case that medical device companies should provide all complaint files for the medical devices to physicians?

MR. JOHNSON: Form.

THE WITNESS: You know, I would say as a general statement, no. But when you -- when you start getting to see signals, I think that's of concern because it's transparency, and it's our ability to really do an adequate informed consent. You know, that's -- or even device selection for us. So I was -- You know, I thought I was in a unique position with Bard; that, you know, I was kind of a consultant with them. I helped them do animal studies to get approval of what I thought were better devices. They never showed me the data of any of the animal studies I did. And then furthermore, they never showed me any of this data that maybe would have been -- I might have had opinions about that might have been helpful for them. And you go why is that? Why -- Why was my opinion not important? And maybe if I had the chance to look at that data I would have said, "I'm not so sure about this test. You know, maybe we need to do more."

You may get to this later, but, you know, they talked to us in 2006 with this consensus agreement, and then they -- they met with me a little bit after that asking

certain things, vague sort of questions about we think our fracture rate is this. Is that a good thing or is that a bad thing? And I -- I was very concerned about that rate. Although if you look at the document, it doesn't convey that. I mean, it's verbiage, so it doesn't convey my concern in the field.

What I was worried about is that in the short period of time that data had accrued, that the rate may eventually go above a rate that I thought was safe. It was going to be beyond what was the standard for the generation of devices at that time. We already looked at tables that show really high numbers, and those are some old numbers that is across multiple different filters and maybe decades of data. But as we get further along, I think the devices should get better.

And so maybe I'm unique because I was a consultant with Bard, and I thought I should have had the information shared with me. But I think that there is other physicians that are in difficult situations with patients that have Bard filters, and I suspect if you ask them, they might say they wished they had known.

BY MR. BROWN:

Q. You mentioned in the beginning of your answer that you think that the company should be providing information when it receives signals; is that right?

Q. Is it your opinion in this case that medical device companies should provide all complaint files for the medical devices to physicians?

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BY MR. BROWN:

Q. You mentioned in the beginning of your answer that you think that the company should be providing information when it receives signals; is that right?

are not referenced in Table 2.

THE WITNESS: I have to look at this. Let's see. Table 2 is two...

(Indicating.)

2, 7, 2, 7, 10, 12, 13. And 12, 13, 24. That's correct, actually. Looks like it's going to be correct. 43.

So I take that statement back. Actually, the way it's worded, it actually is correct. I was reading it, just part of it.

BY MR. BROWN:

Q. First sentence says, "The data evaluated in the medical literature for 2003 and 2011 articles involved past studies, none of which involved retrievable filters," that sentence is not accurate?

A. The first sentence is not accurate. That Table 2 -- That really should apply to Table 2 --

Q. Okay.

A. -- is what -- is the way that should be.

Q. And you wrote Paragraph 220?

A. I don't remember. Sorry. I don't remember.

Q. Do you know who would have written Paragraph 220 if you didn't?

A. Well, I assume it's Dr. Roberts or Dr. Kalva.

Q. Did the plaintiffs provide any drafts of your

report?

A. No. This was -- We wrote this ourselves.

Q. The totality of the report was written by you, Dr. Roberts, and Dr. Kalva; correct?

A. That's correct.

Q. So no pre-worded information was provided to you; these are your own words?

A. No, no. This we wrote ourselves. Yes.

Q. Turning to Paragraph 229, you are referring to testimony by Dr. Clement Grassi, the first named author of the 2001 SIR guidelines?

A. Right.

Q. Do you see that?

A. Yes.

Q. You write, "Dr. Clement Grassi, the first named author of the 2001 SIR article (republished in 2003) and retained expert witness for Bard, testified that the article should not be used and was not intended to be used to indicate safety thresholds..."

And then you cite some testimony by Dr. Grassi.

Do you see that?

A. I do. Yes.

Q. Did you read Dr. Grassi's full deposition?

A. I did. I did.

(Continued on following page.)

MR. JOHNSON: Form objection. Question is also vague.

THE WITNESS: It's a suggestion, but there's -- I don't see them giving a lot of details about how they are doing that. It's -- It's a one-sentence structure with no specifics.

We kind of talked about that, you know, like we talked about whether there is, I don't know, prospective randomized studies, the grades of those versus case studies. There is no mention about how that's done here. I guess we're making assumptions.

MR. BROWN: Okay. Thank you, Doctor. I don't have any other questions for you.

THE WITNESS: Thank you, I think.

MR. JOHNSON: I will have some questions for him. I won't be too long.

-EXAMINATION-

BY MR. JOHNSON:

Q. Doctor, did I understand you to tell us that for a number of years, Bard had you act in different capacities on their behalf?

A. I did many different things for Bard. I did -- I trained physicians on how to put filters in and take them out.

I did animal studies to evaluate new designs.

I participated in the patent lawsuit that had to do with dialysis catheters.

And then I did phone conversations with them, in contact with their clinical support staff or sales personally about particular problems.

Q. All right. And you did that for a number of years?

A. From about 2004 to about 2007 is what I recall.

Q. Who were your primary contact people with Bard? You mentioned Janet Hudnall, for example.

A. Hudnall was one of my major contacts. But I do remember talking to Richard North, I think. He was the guy -- he was the person that contacted me about the phone conversations, if I remember right.

It could have been Dr. Civarella. I don't remember. It's quite a while ago now.

Q. And did you mention Rob Carr?

A. You know, Rob Carr was always in the background, but he -- I didn't -- he didn't solicit me directly. I remember Janet, and I remember either Richard North or Civarella.

Q. Richard North?

A. I think so. Why?

Q. He's an attorney for Bard, defending them in

make if one of your colleagues at one of your hospitals asked you for your advice relating to a problem with a filter?

MR. BROWN: Object to the form.

THE WITNESS: Correct.

BY MR. JOHNSON:

Q. All right. Were you also a trainer for Bard, that is, did you train other physicians on how to implant the filter and explant filters?

A. Yes.

Q. All right. With regard to the report that you prepared for this litigation, does it set forth your opinions within a reasonable degree of medical probability?

A. Yes.

Q. All right. And you told us that you were first retained in this litigation in December of 2016 or January of 2017?

A. I -- I kind of recall January, but I could be wrong about that.

Q. There is a list in your report of Bard documents. Do you recall that?

A. Yes.

Q. And do you recall reviewing all of those documents?

EXHIBIT 02

EXCERPTS FROM DEPOSITION TRANSCRIPT OF SANJEEVA KALVA, M.D.

July 11, 2017

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In re Bard IVC Filters Products Liability Litigation — NO. MD-15-02641-PHX-DGC

ORAL AND VIDEOTAPED DEPOSITION OF
SANJEEVA KALVA, MD
Volume 1 of 1
July 11, 2017

ORAL AND VIDEOTAPED DEPOSITION OF SANJEEVA KALVA, MD, produced as a witness at the instance of the Defendants, and duly sworn, was taken in the above-styled and numbered cause on July 11, 2017 from 9:08 AM to 2:38 PM, before Gaylord A. Sturgess, CSR No. 744, in and for the State of Texas, reported by Stenographic method, at the offices of UT SOUTHWESTERN MEDICAL CENTER, 5323 Harry Hines Boulevard, Room POB1-600, Dallas, Texas 75390, pursuant to the Federal Rules of Civil Procedure and the provisions stated on the record.

I removed Denali. So I have removed all of them but may not have implanted each one of them.

Q. Now, you're obviously an expert in interventional radiology, correct?

A. I believe so.

Q. You would agree that you're not an engineer, however?

A. By training I'm not an engineer. By training I'm a medical person. I have studied medicine, and I became interventional radiologist. I do not have the same engineering background as an engineer would have, if that's the question you're trying to -- the question. But do I understand some of the concepts? I do.

Q. You do not have any prior experience in the design of inferior vena cava filters, do you?

A. Can you rephrase what exactly you mean by that?

Q. Do you have any prior experience in designing inferior vena cava filters?

A. You mean personally?

Q. Yes.

A. So I can tell that, mainly because I am behind the scenes, I have ideas of new filter and that I have not a patent. Yes, I did think about it, but I

have not officially taken patented so far.

Q. You are not a regulatory expert, are you?

A. What do you mean by that?

Q. An expert in FDA regulations.

A. I'm not expert in the FDA regulations, but I know some of the regulations that they impose on physicians how the hospital function. I know those things, but I do not consider myself expert in designing or creating or implementing FDA regulations.

Q. Do you consider yourself an epidemiologist?

A. All medical doctors are -- learn about epidemiology as a part of their medicine. And if you look into any book chapter, any textbook, the first paragraph is always about the epidemiology of the disease. Epidemiology plays a significant role on our understanding of the disease, how resources are distributed.

So epidemiology is learned routinely throughout medicine. So the word epidemiologist is a different question who actually conducts or gets information about epidemiological conditions of a disease process or treatment aspects. But I'm not an epidemiologist, if you're talking about that. But I understand epidemiology is part and parcel of medicine that we learn every day. We practice medicine that

ACR-SIR publications, correct?

A. That is correct.

Q. The list of medical articles here --

A. Yes.

Q. -- is that a comprehensive list of the articles that you and your coauthors utilized in preparing this report?

MR. JOHNSON: Form.

A. We -- we looked into as many as available to us, meaning whatever we search on the PubMed or we got. If anything we have not considered in that document, we are happy to look at them and give my opinion on that.

Q. That's not my question. My question is: Is this the list of doc- -- medical articles that you-all consulted and relied on in doing your report?

MR. JOHNSON: Form.

THE WITNESS: I'm not sure what he's asking.

A. I looked for -- we searched for IVC filters on PubMed, and we got articles. And we selected what we think are relevant and which are not reviewed, which are a little bit more scientific papers that we limited to some articles. And we got them, and we looked at them; and we wrote this document.

So if your question is whether it is comprehensive, comprehensive as much as we could do. Do you think we -- we could have left something inadvertently? It is possible. We might have left inadvertently something.

But technically, if I did, if somebody can find out, that is the reason all the articles go to peer review. Because that is always (unintelligible) by us. And whenever we write papers, even though ten people are involved in the room, we all look into the paper. We think these are the articles that's mostly referenced to this paper. Report them. Then they go to peer review process when we submit to journal.

That peer review goes to three or four different experts in the field through all the world, and they look into it. There are many times those people will tell us, Hey, guys, you forgot this reference. Can you please include this? And it says exactly what you said, but I would like to see that also be included in that.

So there are possibilities that we might have not included inadvertently some articles that are published.

Q. Did you and your colleagues personally

search for these articles on PubMed, or did the lawyers do that?

A. We did. Actually, I did. I don't know how much the lawyers did themselves, but I personally did.

The reason why I did was, I know most of the articles. I was part of the SIR document, and I personally contributed to the document through lot of references. If you see the latest revision completed, previous revision, you might have seen a lot of new references coming into the new document.

And actually, I personally looked into all those articles and then asked the ACR and SIR people to consider them in putting them together into the document. As a matter of fact, we read them. We -- that is part of our life, unfortunately or fortunately. We like to read, we like to learn, we like to see contradictions among sciences, and we make formulations of opinions based on the science.

Q. So you said you like to see contradictions among scientists, correct?

A. Yes. That is part of science.

Q. Well, let's look at the expert reports that you read. You were furnished five expert reports, as I count here; is that correct?

A. Will you show me where you're talking about?

involvement with anterior motor neurons, I will only look at the documents that talk anterior motor neurons.

So just like that, if I'm talking about one particular thing on that, I'll only include that corresponding relevant document. That's all. I think that's there.

Q. I'm not sure I'm following you, Doctor. My question is: How did you decide which internal Bard documents you were going to discuss in this section of the report that you prepared?

A. Whatever re-emphasized my points, that's what I included. Whatever -- so, for example, I talked about filter fracture was a problem. Penetration was a problem. And the document that talk about it in those internal documents, I included them.

Q. Now, my understanding is that sometime in 2005, you and your practice group at Mass General quit using Bard filters; is that correct?

A. That is correct.

Q. And that would be the Recovery filter at that time?

A. Yeah. Recovery filter was the reason why we stopped using Bard filter. We wrote a paper, and it's published in 2006 in Cardiovascular Interventional

number of documents and reports; is that correct?
A. That is correct.
Q. For example, you've seen the report prepared by Dr. Kessler?
A. Yes.
Q. And there are numerous internal Bard documents that are part of that report?
A. That's correct.
Q. Did you look at those documents for the purpose of not only seeing what they reflect but for the purpose of determining whether the opinions expressed by Dr. Kessler were supported by those documents?
A. Yes.
MR. NORTH: Objection, leading.
Q. Did you consider those documents in the Kessler report in rendering your opinions in this litigation?
A. Yes.
Q. In addition, you've had an opportunity to review the report of Dr. Betensky, the Harvard-trained biostatistician?
A. Yes.
Q. You've also had an opportunity to review the report of Dr. Eisenberg --

anything like that.

Q. You also say that you reviewed the company documents that are referenced in the reports of Drs. Kessler and Betensky and Ritchie?

MR. JOHNSON: And Eisenberg, he said.

Q. And Eisenberg. Is that correct?

A. That's correct.

Q. And were those attached to their reports?

A. They were not attached. Whatever he quoted inside the document, I read them. And corresponding documents in the Dropbox, I reviewed them.

Q. So, if you were going to the actual document that's quoted in Dr. Kessler or Betensky or Eisenberg's report, you would be able to find that document in the Dropbox?

A. I believe so.

Q. So there -- all of the company documents you reviewed then --

A. Are in the Dropbox.

Q. -- are in the Dropbox; is that correct?

A. Uh-huh.

Q. Okay.

MR. NORTH: That's it.

MR. JOHNSON: He'll read.

MR. NORTH: We would just to put on the

EXHIBIT 03

EXCERPTS FROM DEPOSITION TRANSCRIPT OF ANNE ROBERTS, M.D.

July 7, 2017

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In re Bard IVC Filters Products Liability Litigation

Case No. MD-15-02641 PHX-DGC

VIDEOTAPED DEPOSITION OF
ANNE CHRISTINE ROBERTS, M.D.
San Diego, California
July 7, 2017
Volume I

Reported By:
Christine E. Milkovits,
CSR NO. 12650

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In re Bard IVC Filters Products Liability Litigation	Case No. MD-15-02641 PHX-DGC

Videotaped deposition of ANNE CHRISTINE ROBERTS, M.D., Volume I, taken on behalf of Defendants, at 4240 La Jolla Village Drive, San Diego, California, beginning at 9:18 a.m. and ending at 6:26 p.m. on Friday, July 7, 2017, before CHRISTINE MILKOVITS, Certified Shorthand Reporter No. 12650.

electronically.

A Mr. Lopez had documents that were available through a drop box. And so I would periodically get some information that there was some files that were available, and then I could download them. And I'm old enough that print tends to work better sometimes than always electronic. So I could print out things as well.

Q Were those documents that he provided to you unsolicited?

A Yes, I guess, that would be most --

Q About how many documents were provided to you via drop box?

A I don't know. Tens -- probably not a hundred but a large number. I didn't always download everything that was available there. Some of the product information I didn't download because there were multiple iterations of the product information, for example.

Q You also mentioned that there were documents that you collected along the way as you did work on this case?

A Right.

Q Can you explain what you mean by that.

A Well, there's documents that --

articles, for example, that we used in terms of generating this report. And so, you know, those articles I downloaded mostly were pubmed. And you'll see, for example, the standards of practice guidelines that were something that I downloaded and printed out.

Q The only medical literature that I see among the documents that you provided in this red file folder are 2003 Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. There look to be two copies of that one from 2001 and 2003. Then an article by Dr. Kinney entitled "Update on Inferior Vena Cava Filters."

A Right.

Q Are there other medical literature that you pulled from pubmed aside from these?

A I've been interested in inferior vena cava filters for many years. And I have folders and folders of articles on inferior vena cava filters which I didn't bring with me.

Q Do those folders and folders -- strike that.

As part of your work on your expert

report in this case, did you specifically pull any other medical literature besides the three articles that are included in this folder that you brought with you today?

A Oh, yeah. You'll see the references in the report. And we -- and so many of those articles are articles that I have either electronically or in print.

Q You mentioned a third way that you obtained documents as part of your work in this litigation.

Other than the drop box and then materials that you just collected along the way -- I forget now what you said -- do you remember what you said?

A I believe I was referring to pubmed. Is that what you were referring to, the electron- -- I mean, it's where you can get articles. You can do a search on whatever you're interested in through the Library of Congress. And -- or excuse me -- National -- I guess it's the National Health Library and you can download articles.

Q Other than the drop box, pubmed, and some additional documents that you received along

to many physicians.
BY MR. BROWN:
Q Are you familiar with all of the regulations, statutes, guidance documents concerning IVC filters?
MR. JOHNSON: Form.
THE WITNESS: I would never say that I'm probably familiar with all of those. I certainly have an understanding of 510 (k) process, a PMA process. I have an understanding of what the FDA has a tendency to look for in terms of those submissions. But I certainly would not hold myself up as knowing every piece of information that is a regulatory thing for IVC filters.
BY MR. BROWN:
Q Have you ever submitted a 510 (k) application for IVC filters since 2000?
A No.
Q Have you ever submitted any PMA application to the FDA since 2000?
A No.
Q Are you an expert in postmarketing adverse event analysis?
MR. LOPEZ: Form objection.
THE WITNESS: I'm certainly aware of the

fact that one needs to submit adverse effect -- or adverse events to -- if we discover them as physicians, that we need to submit them through our risk management group who then will submit those to -- usually to a company, if that's appropriate, or to the regulatory bodies for evaluation.

BY MR. BROWN:

Q Would you agree that you're not an expert in what might constitute a safety signal for a medical device?

MR. JOHNSON: Form objection.

MR. LOPEZ: Same here. I won't do that all -- one objects for both. But sometimes we do both. Sorry about that.

THE WITNESS: I'm sorry. One more time.

MR. LOPEZ: I apologize.

BY MR. BROWN:

Q Would you agree you're not an expert on what might constitute a safety signal for a medical device?

MR. JOHNSON: Form objection.

THE WITNESS: I think that, I guess, I would ask you how you would define a safety signal

trend, which I would think another way of defining that would be a signal that there's a problem with a device, for example.

BY MR. BROWN:

Q But my question is specific to regulations or guidance documents.

Are you familiar with any regulation or guidance documents concerning what might be a signal for a medical device?

MR. LOPEZ: Form objection.

THE WITNESS: I can't say that I am -- that I know that there's a particular regulation that defines that.

BY MR. BROWN:

Q Would you agree that you are not an expert in the contents of IVC filter labelling?

MR. JOHNSON: Form objection.

THE WITNESS: I would say that I have probably -- because of the work that I did at the FDA and the work that I did in terms of helping to write some of that labelling, I would say that I have a pretty good understanding of what labelling is supposed to consist of.

And I would say that my -- probably my understanding of labelling is substantially better

than most physicians probably. So, yes, I would kind of hold myself up as a little bit of an expert in that.

BY MR. BROWN:

Q When did you work at the FDA?

A I worked at the FDA from 1995 to 1996.

Q So 20 years ago?

A Yes.

MR. LOPEZ: Good, Matt. I have a calculator if you need it next time.

THE WITNESS: But I've kept -- I've kept involved since then. So I would say that although the time that I spent there was then -- I've actually kept involved with the FDA first on its circulatory device panel and then through the -- Society of Interventional Radiology we've had meetings with people at the FDA over the years to discuss issues with regards to devices. Or if they need information and they want a way to get some information from the profession, this was a -- this was a mechanism for them to do that.

BY MR. BROWN:

Q You mentioned that you have written IVC filter labelling?

A No, no, not IVC filter labelling. But

those have gone -- been a while ago. But, yeah, I don't think that I -- other than perhaps referencing it that we -- the articles didn't discuss that.

BY MR. BROWN:

Q Have any of the articles, book chapters, or presentations that you've given over the years ever dealt specifically with marketing of IVC filters, meaning what is appropriate marketing and inappropriate marketing?

MR. JOHNSON: Form.

THE WITNESS: Probably not. Although certainly I discussed changes in the use of IVC filters but not specifically -- not specifically the marketing of that.

BY MR. BROWN:

Q Have any of the articles, book chapters, or presentations that you've given over the years specifically concerned the topic of corporate ethics?

A No.

Q Have any of the articles, book chapters, or presentations that you've given over the years specifically concerned the issue of evaluation of 510 (k) submissions for IVC filters?

A Not of IVC filters specifically. I've given a number of talks that talk about the FDA process and 510 (k)s in general, PMAs, that type of thing, but not specifically only about IVC filters.

Q When were those presentations given concerning 510 (k)s and PMAs more generally?

A Oh, I would say after I was at the FDA I gave a lot of talks on the -- how the FDA processes work. Because what became very clear is that many physicians don't really understand that process. And so I was asked to give talks explaining that.

So I gave -- for example, I gave a talk at the School of Engineering here at -- actually, a couple of talks at UCSD explaining to the biomechanical engineers how does a 510 (k) process work, how does a PMA work, what the FDA is looking for, that kind of thing.

I gave a number of talks dealing with clinical trial design. And as part of the clinical trial design how do -- how do you put that clinical trial design in place to get a 510 (k) or PMA. So those were at professional organization.

this one, that, and that one, and the other. We kind of looked -- you know, I would say that we both looked at this and worked on this more as a paper in a way that we had -- were putting together for -- so we would -- as you would write a paper, you would get literature. You would get the, you know, other sources of information and then put them together to create a document.

BY MR. BROWN:

Q You said you would get literature. How would you get literature for this report?

A Well, as I indicated before, we had -- I know I have literature that I collected over the years. And we have -- and pubmed is another source of literature. We both read journals, so there's information from that. And we have experience in putting IVC filters. So I think when you're doing something like this, those are all the sources of information that you tend to put together to come up with a document.

Q How were the articles that are cited in the report at the very end of the report, Appendix A entitled "Facts and Data Considered" -- how were those articles identified for inclusion

in this report?

A Well, by and large because they're articles that pertain to the use of IVC filters.

Q Are you aware that there are over 2,000 articles in the medical literature concerning IVC filters? Yes?

MR. JOHNSON: Form.

THE WITNESS: I would say I am not sure that I know that there are 2,000. But I wouldn't be surprised. And there might even be more.

BY MR. BROWN:

Q So how did you land on 30 or so articles that are listed in the report?

A Well, I think that some of it is -- they're articles that, you know -- I mean, IVC filters is a huge topic. The -- there are some that wouldn't necessarily pertain to this particular issue, and so you wouldn't necessarily use those. And then there's other ones that pertain to this.

So when you look at the articles, you're going to pick out ones that have more relevance to this issue than ones that don't have any relevance to it.

Q Did you have any e-mail correspondence

decisions based on unreliable information could be harmful to patient care?

MR. JOHNSON: Form objection.

THE WITNESS: I guess it depends -- it would really depend on -- unreliable. I mean, if someone is lying about their research, for example, and publishing something that's not true, clearly that would be a problem.

If someone is publishing results that don't contain all of the data or you don't have information about things that have happened so that you're basically left in the dark, that would be unreliable information and would be very problematic in terms of you making good decisions about how to take care of a patient if you don't know what the data is. And if it's concealed from you or not broadcast, you know, so that you know what's going on, then that is really bad.

BY MR. BROWN:

Q My question is about the data itself. If the data itself is unreliable, do you agree that relying on that data to make clinical decisions could be harmful to patients?

MR. JOHNSON: Form objection.

THE WITNESS: I guess I would ask you

recovery in general -- I mean, the recovery specifically.

BY MR. BROWN:

Q Did you consider data that weighed against the opinions included in your report?

MR. JOHNSON: Form.

THE WITNESS: Yeah. I mean, we looked at the -- we looked at the literature in terms of a Bard filter and filters in general as part of our putting together this report.

BY MR. BROWN:

Q If you ignored data that weighs against the opinion that Bard's filters are defective, would you agree that you wouldn't be applying the same level of intellectual rigor for your work in this case as you do in your private practice?

MR. JOHNSON: Form objection.

THE WITNESS: Well, if we had ignored data, that would not be particularly -- I mean, we would not do that. If you have data that we didn't consider, I'll be more than happy to look at that data and make sure that it's, you know, part of any further work that we do on this case. But, you know, like I say, we went through the literature and these were our conclusions. And if

I mean, he's an extraordinarily well respected physician. Clearly has enormous expertise, particularly having to do with his position at the FDA and his position in academic medicine and had -- from reading his report and then going back to some of the source documents and looking at those and understanding those -- or looking at those in the context of his report, I think gave us a, you know -- we would certainly quote him because we wouldn't want to be saying that we had made this up ourselves.

BY MR. BROWN:

Q Do you have any idea of the methodology that Dr. Kessler employed in the -- reaching the opinions that he sets forth in his report?

A Well, only that in the report -- you know, my recollection is that he discusses looking and references, you know, multiple, multiple documents which were obtained from Bard in terms of putting together sort of a chronology of what went on, you know, looking at their -- looking at the data that, you know, was available.

And so, I mean -- but it's quite clear -- I mean, he references multiple -- and I did go back and look at some of those memos and some of

those references to see -- to get a feeling of how he characterized those. So I felt quite comfortable after looking at sort of the source material and looking at his report that it seemed to jive.

Q But you don't know how Dr. Kessler went about identifying the documents that he chose to cite in his report, do you?

MR. JOHNSON: Form.

THE WITNESS: I have not discussed it with Dr. Kessler as to how he decided to, you know, take the documents that he talked about and put them in his report. So, no, I haven't had any discussion with him about that.

BY MR. BROWN:

Q In all of the articles that you've written, in all of the prerequisites that you've made, have you ever cited to a paid litigation expert?

MR. JOHNSON: Form.

THE WITNESS: I don't think I've ever been in the position where I was needing to quote a litigation expert because that's not usually the kind of work that I do.

///

Q And perception of physician does that mean what the physician is -- knows about the safety profile of a device --

MR. BROWN: Object to the form.

BY MR. LOPEZ:

Q -- such as an IVC filter?

MR. BROWN: Calls for speculation.

THE WITNESS: Well, I think that the degree of disclosure it -- I think that in this case that the degree of disclosure is what the physician knows and is able to tell the patient. So it -- it's going to -- if you know about a problem, then you should disclose that problem. If you don't know about it, obviously you're not going to be able to disclose it.

BY MR. LOPEZ:

Q Would you agree that the perception of a physician might have about the safety and effectiveness of a device, at least based on what you've seen in the Bard documents, depends in large part on what the manufacturer tells physicians or conceals from physicians?

MR. BROWN: Object to the form.

THE WITNESS: Yes. I think that the perception would -- you know, if you don't know,

EXHIBIT 04
FILED UNDER SEAL

EXCERPTS FROM DEPOSITION TRANSCRIPT OF DONNA-BEA TILLMAN, Ph. D.

August 4, 2017

(Filed Under Seal)

EXHIBIT 05
FILED UNDER SEAL

EXCERPTS FROM DEPOSITION TRANSCRIPT OF CLEMENT J. GRASSI, M.D.

June 15, 2017

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

No. MD-15-02641-PHX-DGC

****

IN RE BARD IVC FILTERS PRODUCTS

LIABILITY LITIGATION

****

DO NOT DISCLOSE

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF CLEMENT J. GRASSI, MD

Thursday, June 15, 2017

9:24 a.m.

Held At:

Nelson Mullins Riley & Scarborough LLP

One Post Office Square

Boston, Massachusetts

REPORTED BY:

Maureen O'Connor Pollard, RMR, CLR, CSR

And the question is, if the filter had a greater risk over time to the patient, should doctors be made aware of that?

MR. BROWN: Object to the form. Asked and answered.

A. I believe I have answered that, because it is not my opinion, and I haven't presented -- been presented with any information that shows that there's a greater risk over time when used as a permanent device.

BY MR. ROTMAN:

Q. I wasn't asking you about whether you've been shown evidence of it. I'm asking you a hypothetical.

If -- you realize that there are conclusions stated in the papers that I showed you earlier today and in others that disagree with you about that point, about risk over time, correct?

A. I understand your point.

Q. Okay. So I'm asking you if they're right and you're wrong on this issue about risk over time, if there is an increased risk over time, is that something that doctors should be

advised about --

A. Well, let me say this.

Q. -- so that they can give the best safe treatment for their patients?

MR. BROWN: Object to the form.

A. Let me say this, that if that condition existed with a significant risk increase, then I would expect physicians in a summary fashion to be informed about it.

BY MR. ROTMAN:

Q. Do you expect a manufacturer will adequately test a product before it's put out on the market? And I mean a device manufacturer.

A. Yes.

MR. BROWN: Object to the form.

BY MR. ROTMAN:

Q. And you also expect a device manufacturer to follow the federal regulations on postmarketing surveillance, correct?

A. Yes.

Q. And just like doctors should be informed if there is a greater risk over time of having a filter implanted, patients should also have that information provided to them, correct?

A. As part of an informed consent, patients should have information provided that is relevant to them and to their procedure.

Q. You would agree that there have been no long-term studies performed on the Bard retrievable filters?

MR. BROWN: Object to the form.

BY MR. ROTMAN:

Q. Would you agree that there have been no long-term studies on Bard retrievable filters?

MR. BROWN: Object to the form.

A. No, I'm afraid I can't agree with that. For example, I can think of a paper which was published by a colleague of mine, Christoph Binkert, in which he looked at the retrievability and recovery of vena caval filters longer than 180 days. And so depending on in your question what you consider to be long, there have been studies, or there have been clinical reports, some retrospective, in which interventional radiologists or other radiologists have looked at vena caval filters and have summarized what has been the

COMMONWEALTH OF MASSACHUSETTS)
SUFFOLK, SS.)

I, MAUREEN O'CONNOR POLLARD, RMR, CLR, and Notary Public in and for the Commonwealth of Massachusetts, do certify that on the 15th day of June, 2017, at 9:24 o'clock, the person above-named was duly sworn to testify to the truth of their knowledge, and examined, and such examination reduced to typewriting under my direction, and is a true record of the testimony given by the witness. I further certify that I am neither attorney, related or employed by any of the parties to this action, and that I am not a relative or employee of any attorney employed by the parties hereto, or financially interested in the action.

In witness whereof, I have hereunto set my hand this 17th day of June, 2017.

_____

MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC
Realtime Systems Administrator
CSR #149108

EXHIBIT 06
FILED UNDER SEAL

EXCERPTS FROM DEPOSITION TRANSCRIPT OF CHRISTOPHER D. GANSER.

October 11, 2016

(Filed Under Seal)

EXHIBIT 07

ARTICLE

Robert J. Myerburg, MD, et al., *Life-Threatening Malfunction of Implantable Cardiac Devices*, 354:22 NEW ENG. J. MED., June 1, 2006, at 2309 and 2311.

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

JUNE 1, 2006

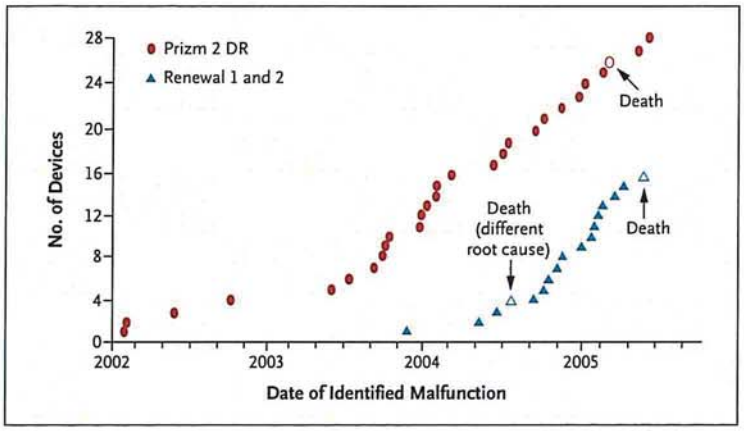
Life-Threatening Malfunction of Implantable Cardiac Devices

Robert J. Myerburg, M.D., David W. Feigal, Jr., M.D., M.P.H., and Bruce D. Lindsay, M.D.

During the summer of 2005, in the wake of widespread criticism of its failure to communicate the potentially fatal malfunctions of its implantable defibrillators,[1,2] Guidant Corporation created an independent panel, of which we were members. The purpose of the panel was to conduct an unbiased examination of these incidents, including the methods used to identify the malfunctions and evaluate products in the postmarketing phase and the policies regarding communication within the corporation and with physicians and patients. The panel was also asked to recommend corrective actions. Concurrently, the Heart Rhythm Society — which represents physicians who implant cardiac devices — established a task force to examine assessments of device performance and develop policy recommendations and guidelines.[3] Since the report by the independent panel had implications for the device industry in general, Guidant made it available to the public.[4]

Three points quickly emerged as guidelines for the panel's deliberations. First, manufactured products can never be entirely free of design or manufacturing flaws, but when the consequence of a malfunction is a potentially fatal event, tolerance and surveillance strategies should aim to achieve a risk of malfunction that is as close to zero as possible. Second, physicians must know about the performance features of any device they recommend for a patient, so that they can carry out their ethical obligation of obtaining informed consent. This information must be in a form that is understandable and clinically useful. And third, patients have a right to obtain product information so that they can make informed decisions about risks and benefits and can understand what expectations are reasonable.

The panel recognized that, as compared with the clinical benefit of implantable cardiac devices, the rate of serious malfunctions is very low. We also concluded, however, that if a malfunction is life-threatening, even a low risk of its occurrence takes on importance beyond its numbers. Although it is intuitively clear that any manufactured product will have a measurable failure rate, until recently, industry had not provided information to physicians about potentially serious malfunctions when the failure rates fell within the overall performance predic-



Defects Leading to Potential Failure in Two Types of Guidant Implantable Defibrillators.

The numbers of implantable defibrillators identified between 2002 and mid-2005 as having defects that predisposed them to short-circuiting (arcing), with an attendant risk of failure to deliver therapy when needed, are shown. The Prizm 2 DR was a conventional implantable defibrillator, and Renewal 1 and 2 were implantable defibrillators with biventricular pacing capability. Open symbols represent malfunctions that were associated with the death of a patient; one of these malfunctions was due to a random manufacturing defect rather than to the identified defect that resulted in short-circuiting ("different root cause"). Adapted from Myerburg et al.[4]

tions.[4] In most cases, these malfunctions were simply folded into overall statistics that also included less critical malfunctions and the expected depletion of batteries over time — a practice that made serious but infrequent malfunctions invisible to physicians and patients.

Although there is no industry-wide performance standard for malfunction rates in the cardiac-device industry, all companies are required by the Food and Drug Administration (FDA) to evaluate device malfunctions systematically in the post-marketing phase, to identify those that are clinically significant, to correct defects, and to act to prevent failures in performance. These internal processes necessarily center on engineering skills and methods. But the consequences of device malfunctions are more than an issue for engineering: they have clinical implications for patients that may include a risk of fatal events. Thus, engineering performance standards are insufficient benchmarks without evaluation by experts of the possible effects on individual patients. The independent panel concluded that the lack of adequate clinical expertise, combined with undue reliance on arbitrary statistical criteria, led to decisions that had potentially and manifestly serious consequences. The graph shows the number of implantable defibrillators that were identified as having defects that predisposed them to short-circuiting (arcing) between 2002 and 2005.

As the number of defibrillators with life-threatening malfunctions continued to grow, the overall reliability of the products remained within the predicted rates. Therefore, in keeping with the company's standard practices at the time, the engineering group at Guidant decided, without any input from physicians, that it was unnecessary to inform physician-customers about these events.[4] In addition, implantations of the potentially defective defibrillators continued for a time, and physicians, hospitals, and patients were not informed that the devices had flaws that could result in the inability to deliver therapy when necessary. It seems clear that the industry needs physicians with defined responsibilities focused on patient safety to provide recommendations to corporate leaders.

Post-marketing surveillance continues to be a challenge for the FDA and industry. Clinical trials rarely identify significant signals of very uncommon adverse events, and only a small proportion of later events are ever reported. One potential solution to this limitation of tracking, at least for cardiac devices, lies in the National Cardiovascular Data Registry mandated by the Centers for Medicare and Medicaid services for implantable cardioverter–defibrillators, which could be expanded and adapted to other databases. Moreover, the number of malfunctions that occur at the time of deaths that are assumed to be from natural causes remains unknown, because most devices are not returned to manufacturers for evaluation after patients die.

The FDA recently announced plans to address post-marketing surveillance more actively, including having electrophysiology experts from its Circulatory System Devices Panel review the post-marketing performance of implantable devices. The Heart Rhythm Society's task force also suggested that the FDA establish post-marketing advisory committees to recommend actions that should be taken when malfunctions are identified in defibrillators or pacemakers.[5] These steps could help the FDA address many issues, in-

cluding the lack of standard definitions and classifications of malfunctions that makes evaluating reports from different manufacturers problematic. It is uncertain whether the FDA could appreciably enhance the effectiveness of its post-marketing surveillance program without expanding both its authority and its budget. But if patient safety is a priority, the federal government should appropriate the funds required to make this effort feasible, without adversely influencing the FDA's other areas of responsibility.

In the meantime, companies must reevaluate their approach to patient safety in the context of communication. A critical question is when and how information about product performance should be communicated to physicians and patients. Although the issues — both ethical and practical — are complex, one conclusion is clear: transparency in matters that affect patient safety should be embraced as a primary corporate obligation.

In the past, this industry has not had a good record of open communication, but transparency does benefit companies that want to be viewed as trusted partners in the health care enterprise. As the panel noted, transparency may be passive, with information made available to those who seek it; active, with information targeted to specific groups of stakeholders; or forced, with a third party bringing forth information that elicits further disclosure by a company, as a defensive move. From the perspective of physicians' and patients' expectations, corporate responsibility, and public perception, we believe that proactive communication policies, centering on the proper use of active and passive transparency, should be the norm. Insofar as such communication is hindered by perceived business conflicts, the solution may lie in new regulatory definitions that distinguish informational actions from those that indicate the removal of a device. Changing language can be difficult, since much of it is embedded in statutory requirements.

The panel also recommended that Guidant establish an independent review group to provide unbiased analysis of information on product performance and advice on decisions about external communications. Voluntary, independent review at the level suggested is a notion both foreign and frightening to most corporations, whose perceived need is to protect business interests. But corporate culture fosters a loyalty to corporate goals that may create unintended bias and distorted perceptions about product performance and patient safety. Independent review groups could assist corporations by generating unbiased advice that was responsive to society's view of the best business practices and clinical priorities.

Historically, corporations have — by themselves — set the expectations for device reliability and the communication of product malfunctions, seeking little input from patients, physicians, or professional organizations. This practice developed in the early years of the industry, when the combination of small numbers of device recipients and low malfunction rates made it difficult to detect problems. With the explosive growth of the industry in recent years, previously unrecognizable signals have become increasingly visible. Clearly, strategies for evaluating and communicating device malfunctions must be adjusted accordingly. Our conclusion is that industry should work collaboratively with physicians, professional societies, patient representatives, and regulatory agencies to establish reasonable standards and guidelines for the device industry to follow. Patients deserve nothing less.

The opinions expressed in this article reflect the views of the authors and are not endorsed by Guidant or any of the institutions or organizations with which the authors are affiliated.

Drs. Myerburg, Feigal, and Lindsay report having received honoraria from Guidant. Dr. Myerburg also reports having received consulting fees from Procter & Gamble and Reliant and having served as an expert witness. Dr. Lindsay reports having received consulting fees from Medtronic.

This article was published at www.nejm.org on May 15, 2006.

Dr. Myerburg is a professor of medicine and physiology at the University of Miami Miller School of Medicine, Miami. Dr. Feigal is a partner at NDA Partners, Phoenix, Ariz., and the former director of the Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Md. Dr. Lindsay is an associate professor of medicine and director of cardiac electrophysiology at Washington University School of Medicine, St. Louis.

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EXHIBIT 08
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EXHIBIT 09

Ex. 3 to Schultz Dep.,

G3 Vena Cava Filter Design Input Summary

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1.0 Purpose

This report documents and summarizes the design input information gathered during the concept phase of the G3 Vena Cava Filter project. This design input information is used to develop the Product Performance Specification (PPS), product design, and test plans. The business case for this project is outlined in Product Opportunity Appraisal POA-8049.

2.0 Scope

This design input summary applies to development of the G3 Vena Cava Filter. This report will document design input specific to the this product, as well as additional information related to actual use conditions and complaint data received on our currently marketed IVC Filters.

3.0 Information Sources

Design input information was gathered from multiple sources. These included the following:

- Discussions with clinicians who perform IVC Filter placement and retrieval procedures
- Focus group interviews with Interventional Radiologists, Trauma Surgeons, Bariatric Surgeons, Hematologists, Internal Medicine and Vascular Medicine specialists
- Market Research Studies
- Clinical Literature Review

- Complaint review
- MAUDE website review
- Regulatory requirements review

4.0 Project Background Information

BPV launched the Recovery Vena Cava Filter (RF-048F) with a permanent indication in April 2003, followed with the retrievable indication in October 2003. As the first IVC filter to receive a retrievable indication in the U.S., Recovery Filter brought a new level of awareness within the medical community to filter technologies and their associated complications.

Traditionally, permanent filters were placed primarily in patients with documented thromboembolic disease and a contraindication to or complication with anticoagulation. These patients typically received a filter during their hospital course and then were never follow up specifically for the filter. With newer, retrievable filters, not only are more patients receiving filters, but they are being followed at a higher rate due to the intent to retrieve the filter. The implication of this updated follow up regimen is that more asymptomatic filter complications are being discovered than ever before.

BPV discontinued the Recovery Filter in September 2005 and immediately replaced it with the G2 Filter (RF310F, RF210F), which has a permanent indication. As part of the routine passive post-market surveillance program, BPV began receiving reports of caudal migrations of the G2 Filter. Although the rate of caudal migration has always remained well below the reported rates in the SIR Quality Improvement Guidelines for IVC Filters, BPV undertook the effort to modify the design of the G2 Filter to improve its caudal migration resistance.

5.0 Summary of Design Input

Migration (both cranial and caudal) is a known and well-documented complication of vena caval filters. Although most agree that caudal migration is not the most serious of filter complications in terms of patient safety, it is nevertheless worrisome for most physicians when they encounter one of their patients with a filter that has migrated caudally.

Numerous sources and methods were utilized to determine the design input for this project. The main goal of the efforts was to determine the expected and threshold complication rates for IVC Filters. Below is a summary of the information gathered from each input source.

5.1 Literature Review

5.1.1 A comprehensive review of the available literature revealed that although caudal migration is not the most serious of possible filter complications, some filters in history have undergone redesign efforts (Titanium Greenfield) or were discontinued entirely (Gunther) due to caudal migration.

5.1.2 A secondary review of the available literature detailed the necessity of certain vena cava filter characteristics. These characteristics included (in no specific order):

- Self-Centering and Tilt Resistance
- No arm/leg entanglement (crossed limbs)
- Efficient clot trapping
- Caval patency
- Low profile
- Extended retrievability
- Easy retrieval
- Fracture resistance
- Migration resistance
- Filter sized accordingly (one sized filter fits most vena cava)
- Ability to power inject
- Accurate deployment
- Deployment with minimal force
- Perforation

The corresponding clinical literature is provided in Appendix G.

5.2 Market Research Studies

5.2.1 Bard Customer Surveys

A survey of Bard customers regarding their IVC Filter utilization was conducted in Q1 2005. Respondents were recruited by telephone and asked to fax back a 3-page questionnaire. A total of 154 surveys were completed and returned.

One of the questions in the survey assessed the problems that users have had with various types of optional filters. The responses showed a trend toward a higher (perceived) rate of migrations, perforations, and filter tilt with Bard's filter than the Gunther Tulip (Cook) or the OptEase (Cordis).

Q: Problems experienced with optional filters, by brand (n=154, multiple answers were accepted)

	Recovery (Bard)	Gunther Tulip (Cook)	OptEase (Cordis)
Filter tilt	38%	33%	3%
Inability to retrieve	24%	19%	11%
Filter migration	14%	3%	2%
Caval perforation	9%	3%	1%
Caval thrombosis	6%	11%	14%
Filter fracture	5%	3%	0%
Death	3%	1%	1%
Inadequate indwelling	1%	3%	3%
Other	5%	3%	5%

None	43%	55%	73%

5.2.2 Bariatric Surgeon Surveys

Another survey was completed in Q1 2005 involving Bariatric Surgeons and their filter utilization. The aim of this study was to assess bariatric surgeons' awareness of IVC Filter technology and the possible risks and benefits associated with caval interruption. Respondents were once again recruited by telephone and asked to fax back a 4-page questionnaire. A total of 90 completed surveys were returned.

One of the questions in this survey illustrated bariatric surgeons' general knowledge/perception of the types of complications that can occur with filters and how often:

Q: How often do you observe the following complications due to IVC Filters In your patients? (n=90)

	< .1% (Less than 1/1,000)	1% (1/100)	5% (5/100)	>5% (over 5/100)	Do Not See
Filter migration	41%	19%	4%	1%	34%
Caval Thrombosis	34%	20%	9%	1%	36%
Caval perforation	43%	9%	1%	0%	47%
Filter fracture	43%	6%	1%	0%	50%
Death	47%	6%	0%	0%	48%

The responses to the above question indicate that bariatric surgeons do and expect to see complications with filters. The majority expects to see these filter problems at a rate less than 1/1,000 cases.

5.3 Focus Groups

5.3.1 Multidisciplinary Panel

In June 2004, BPV convened a multidisciplinary panel of physicians with specific expertise and/or interest in thromboembolic disease and IVC Filters to discuss filter complications. This panel discussed many issues including expected and threshold rates for various filter complications and possible causes for these filter problems.

With regard to filter migration, the panel's perspective was the following.

- It should occur less than 1% of time
- For prophylactic filter placement, migration to the heart should virtually never happen. The rate should be less than 1 in 1,000.

- Migration should not be different for retrievable filters than for permanent filters.

It should be noted, however, that this discussion was mainly about proximal (or cranial) migration.
For caval perforations, the panel believed that symptomatic perforations should be less than 1% and that the rate of asymptomatic perforations does not matter.

In summary, the multidisciplinary panel felt the following about general filter performance:

- A retrievable filter is expected to perform just as well as a permanent filter.
- A filter should not migrate; no matter what the size of thrombus burden it captures.

5.3.2 Key Opinion Leader/High Volume User Panel

BPV convened another panel in June 2006 to discuss caudal migration of filters, specifically the BPV experience to date with the G2 Filter. This panel included Key Opinion Leaders and High-Volume users of IVC Filters. The list of panelists along with their profiles is included as Appendix D.

Below are some highlights of the discussion:

IVC Perforation:
- Could lead to erosion into duodenum, perforation of aorta, lodge in vertebral body
- OK if asymptomatic, but could become symptomatic over time
- 0 – 1% for "true" peforation; most perceived perfs are not "true" perforations
- Belief there is strong correlation between tilting and perforation

Migration (More than 2cm):
- Concern when goes to heart/lungs or goes from infrarenal vs suprarenal or symptomatic migration or in combination with tilt/perforation
- More concern over cephalad migration vs caudal migration
- Theoretical concern if filter migrates caudally, since there is more space above filter in the IVC for thrombus formation (source for recurrent PE)

BPV Experience:
- Should focus on symptomatic complications – asymptomatic events probably occur at a much higher rate because underreported
- At the time of the Expert Panel, there had been 3 symptomatic migrations in females: panelists thought these were coincidental in relation to small IVC diameter. Also, suggested females experience more abdominal & pelvic pain; therefore, may not be of real concern.
- The panelists expressed concern over 3 suprarenal caudal migrations vs 4

infrarenal that had been reported as of the date of the Panel. This does not represent actual placement practice: 100 infrarenals to 1 suprarenal.
- Generally, believe most migrations occur early (first 2 weeks) due to healing process
- Horizontal orientation: higher clot trapping efficiency may indicate higher risk of caval thrombosis and greater risk of pain due to stretching IVC
- Felt reassured by BPV's due diligence with clot trapping study
- Suggested IVC diameter may play role in caudal migration and tilting could lead to pain (symptomatic) in patients with smaller IVC due to stretching

Summary of Concerns Expressed:
- Inability to remove
- "True" migrations
- PE due to filter failure
- Concern with caudal rates but not in relation to other filters

Dr. Oliva Experience at CHUM:
- Of 40 attempted retrievals 24 anticoagulation contraindicated. 8 need prolonged filtration.
- 1 Caudal migration of 23 retrievals
- 17% tilting, some associated with perforation/penetration
- Retrieval window: 44 days (7 – 128)

Potential Root Causes for Caudal Migration:
- Believe most influential factor is caval dimensional changes
- Watermelon seed affect
- Small cava....more likely because arms may allow filter to ski down
- Large cava... arms more likely to catch and prevent downward migration
- Not much vessel spasm in IVC, but there is in small vessels

5.4 Field Visits

Numerous field visits were conducted by BPV sales, marketing, and R&D to respond to questions regarding various filter issues, including caudal migrations. These visits were also utilized to gather information regarding users' expected and threshold rates of various filter complications.

The main message that came out of the clinical interviews conducted during field visits is that users who have experienced caudal migrations of the G2 Filter are generally unhappy with the rate of this failure mode they are seeing. The users' perceived rate of caudal migrations seem to have a strong positive relationship with retrieval rate, as can be seen in the below table, which is a representative depiction of the general opinion based on utilization and retrieval rate.

Physician	Hospital	Annual Utilization	Retrieval Rate	Perceived caudal migration rate (G2 Filter)

Frank Lynch, MD	Hershey Penn State Hershey, PA	200 – 250 units	50%	30%
Mamood Razavi, MD	St. Joseph's Hospital Orange, CA	50 – 75 units	15%	1%
Bruce Zweibel, MD	Tampa General Hospital Tampa, FL	150 – 200 units	>5%	0%

Although most physicians believe that caudal migration has less serious patient safety implications than some other types of filter complications, they believe that a filter that moved caudally implies a general instability of the device in situ and therefore felt less comfortable using it as their default filter.

A summary of the field visit log, along with a justification of which of these design inputs will or will not be pursued as part of the G3 Filter project is located in Appendix F.

5.5 Complaint analysis

A thorough review of all received internal filter complaints was completed by conducting a search within Trackwise (BPV's internal complaint tracking software) by FDA code for both the currently marketed filter devices (Simon Nitinol Filter, G2 Filter, and Recovery Cone), as well as historically marketed filter devices (Recovery Filter). A detailed list of all complaints, shown by FDA code is shown in Appendix H. In summary, the top five complaints as of July 31, 2007 for each filter product are shown in the table below.

Filter Type	Top Five Reported Complaints				
	#1	#2	#3	#4	#5
SNF	Difficult to Deploy (QTY: 41)	Failure to Deploy (QTY: 26)	Twisting (QTY: 19)	Dome Collapse (QTY: 10)	Detachment of Components (QTY: 7)
Recovery	Detachment of Components (QTY: 123)	Migration* (QTY: 61)	Difficult to Deploy (QTY: 31)	Twisting (QTY: 31)	Perforation (QTY: 29)
G2 Femoral	Difficult to Deploy (QTY: 99)	Failure to Deploy (QTY: 73)	Migration** (QTY: 45)	Misplacement (QTY: 25)	Missing Components (QTY: 18)
G2 Jugular	Migration*** (QTY: 17)	Other**** (QTY: 7)	Broken Components (QTY: 5)	Twisting (QTY: 4)	Perforation (QTY: 4)
Recovery Cone	Detachment of Components (QTY: 26)	Broken Components (QTY: 7)	Bend (QTY: 4)	Failure to Capture (QTY: 4)	Other (QTY: 4)

*The majority of these migrations were in the cranial direction
**37 of these migrations were caudal, 8 were cranial
***All of these migrations were in the caudal direction
****Typically 'other' encompasses tilt and delayed opening

As well, a review of the MAUDE database was conducted, comparing the

complaint rates of all commercially available filters against the SIR Guidelines. It is important to keep in mind that companies are only liable for reporting medical device reports (MDRs) for those complaints that they determine could or have caused patient injury. Each company uses their own internal standards for making this determination, thus, there potentially exists a wide range of discrepancy from company to company on what complaints are reported to the FDA. A summary of the MAUDE database findings, as well as a ranking by company for each complaint type are provided in Appendix H.

5.6 Current Regulation Review

A review of the following regulations was completed:

- Guidance for Cardiovascular Intravascular Filter 510(k) Submissions, November 26, 1999
- Smith, Angela. Regulation of Peripheral Vascular Devices: Current issues in the regulation of IVC filters. Endovascular Today; Nov. 2005: 93-94
- Shelf Life of Medical Devices, April 1991
- Sterile, single-use intravascular catheters, ISO10555-1:1995
- Non-active surgical implants – General Requirements, ISO14630:1997
- Non-active surgical implants – Particular requirements for cardiac and vascular implants; Part 3: Endovascular devices, EN12006-3:1999

From this review, many additional regulatory requirements were identified, including, but not limited to: biocompatibility, simulated deployment, introducer/sheath suitability, clot trapping ability, filter fracture, caval perforation filter migration, thrombogenicity, MRI compatibility, and many more. The detailed requirements can be found in Appendix I.

Description of Change—

Revision number	Changes
000	Original/J.Hudnall
001	Updated project name from Tetra to G3 throughout, updated Appendix F to include rationale for user needs, changed document number from TD-00395 to DIS-8049/S.Klocke

Appendix A

Vena Cava Filter Usage Study
Among Bard Customers
Final Report

Appendix B

Vena Cava Filter Usage Study
Among Bariatric Surgeons
Final Report

Appendix C
Multidisciplinary Panel
Summary Report

Appendix D

Key Opinion Leader/High-Volume User Panel
Panelist Profile

Appendix E

Key Opinion Leader/High Volume User Panel Meeting Summary

Appendix F
Field Visit Log

Appendix G
Clinical Literature

Appendix H
Complaint Data

Appendix I
Regulatory Requirements